

4/1/99

NOVAFIL** AND VASCUFIL**

K990952

NONABSORBABLE, MONOFILAMENT SURGICAL SUTURES

V. 510(k) Summary of Safety and Effectiveness

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Victor M. Clavelli

DATE PREPARED: March 18, 1999

CLASSIFICATION NAME: Polyester Sutures

COMMON NAME: Polyester Sutures

PROPRIETARY NAME: Novafil** and Vascufil**

PREDICATE DEVICES: Novafil** and Vascufil**

DEVICE DESCRIPTION: Novafil** non-absorbable monofilament surgical sutures are composed of polybutester, a copolymer of butylene terephthalate and polytetramethylene ether glycol.

Vascufil** coated non-absorbable monofilament surgical sutures are composed of polybutester, a copolymer of butylene terephthalate and polytetramethylene ether glycol. The suture is coated with POLYTRIBOLATE**, an absorbable polymer of e-caprolactone / glycolide / poloxamer 188.

INTENDED USE: Novafil** and Vascufil** Sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic surgery, but not in microsurgery and neural tissue.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1999

Mr. Victor M. Clavelli
Manager, Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K990952
Trade Name: Novafil and Vascufil Sterile Synthetic Nonabsorbable Sutures
Regulatory Class: II
Product Code: GAT
Dated: March 19, 1999
Received: March 22, 1999

Dear Mr. Clavelli:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Friday, May 31, 1991 (Vol. 56, No. 105, Pages 24684 and 24685). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the devices, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Novafil and Vascufil Surgical Sutures are indicated for use in general and soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic surgery, but not in microsurgery and neural tissue.
2. These devices may not be manufactured from any material other than high molecular weight fibers composed of long chain linear polyester having recurrent aromatic rings as an integral component. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Novafil and Vascufil surgical sutures. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified devices.

The sale, distribution and use of these devices is restricted to prescription use in accordance with 21 CFR 801.109.

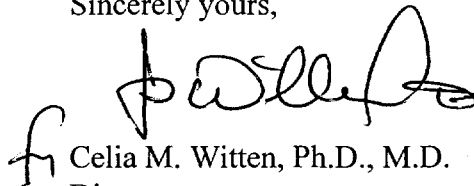
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your devices can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, The Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control Provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

NOVAFIL AND VASCUFIL****
NONABSORBABLE, MONOFILAMENT SURGICAL SUTURES

III. Indications For Use:

510(k) Number (if known): K990952

Device Name: Novafil** and Vascufil** Sterile Synthetic Non-absorbable Sutures

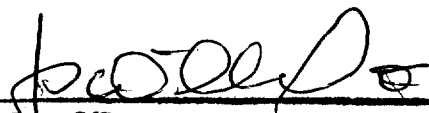
Indications For Use:

Novafil** and Vascufil** sutures are indicated for use as non-absorbable sutures in general and soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic surgery, but not in microsurgery and neural tissue.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990952